REMARKS

Claims 15, 17-23, 26, and 32-40 are rejected. Claims 1-14, 16, and 25 were previously canceled while claims 24 and 27-31 were previously withdrawn. Claims 15, 19, 21, 26, 37, and 39 have been amended while claims 33 and 38 have been canceled herein. Therefore, claims 15, 17-24, 26-32, 34-37, 39, and 40 are pending and at issue. Applicants respectfully request reconsideration of the rejections and allowance in light of the foregoing amendments and the following remarks herein.

As an initial matter, Applicants are submitting herewith a Request for Continued Examination. Therefore, Applicants respectfully request entry of the present Amendment.

Claim Rejections — 35 U.S.C. § 112

Claims 26 and 37-39 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter. Applicants have amended many of the claims and present the following comments.

Claim 26 is rejected regarding the phrase "kit or device…comprising…antibodies effective for …and substrate effective for…." Applicants have amended the claim to delete the phrase "or device" from claims 26 and 37-39. Therefore, this rejection should be withdrawn.

Claim 26 is rejected regarding the term "effective" as allegedly being subjective. Applicants respectfully disagree with the Office Action's characterization of this term. Applicants have set forth a number of different materials, components, procedures, etc. such that one skilled in the art would readily understand what the term means. More specifically, one skilled in the art would understand the phrasing of "antibodies effective for immunocapturing the enzyme" and "a substrate effective for detecting and/or measuring" in view of the present application and detailed description, including the numerous examples explained therein. Therefore, this rejection should be withdrawn.

Claim Rejections — 35 U.S.C. § 102

Claims 15, 17-19, 23, 26, 32, 37, and 40 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Deby et al. U.S. Patent No. 5,460,961 ("Deby et al."). This rejection should be withdrawn as Deby et al. fails to disclose or suggest one or more features recited in the claims.

Claim Amendments

The Office Action at the last paragraph on page 4 through the first paragraph on page 5 asserts that a number of the features recited in the preamble were not given patentable weight. Applicants disagree with this characterization of the preamble and language therein as the previous form of the claims did refer back to the enzymes discussed in the preamble thereby inherently incorporating many of the features into the body of the claim. However, Applicants have amended the claims to more directly refer to the source of the enzymes as well as the enzyme activity.

More specifically, Applicants have amended independent claims 15 and 26 to more clearly recite the features therein and hopefully clear up any confusion regarding the present claims and the cited references. More specifically, the claims have been amended to recite immunocapturing the enzyme released by the neutrophil cells. Additionally, the claims have been amended to recite detecting and/or measuring the activity of the immunocaptured enzyme present which indicates the activation status of the neutrophil cells in the biological sample. Therefore, as these features are specifically recited in the body of the claim, they must be given patentable weight.

Deby et al. Fails to Disclose or Suggest Detecting and/or Measuring the Activity of the Immunocaptured Enzyme

As noted above, the claims recite immunocapturing the enzyme released by the neutrophil cells and then detecting and/or measuring the activity of the immunocaptured enzyme present which indicates the activation status of the neutrophil cells. Deby et al. fails to disclose or suggest such features. In one form, the features described in the present application provide for detection of the enzymatic activity of myeloperoxidase bound to antibodies. Deby et al., on the other hand, is directed to detection of myeloperoxidase, not to the measurement of its enzymatic activity. For example, Deby et al. describes at col. 21, lines 37-64 that alkaline phsophatase activity is measured which reflects the total MPO and not the active MPO. Moreover, it is the alkaline phosphatase activity which is measured, not the activity of the bound MPO, such as in the present application. Therefore, this portion of Deby et al. is directed to detection of an entirely different material (alkaline phosphatase) and not detection of the activity of the immunocaptured enzyme released by neutrophil cells.

Deby et al. also describes at col. 21, line 64 through col. 22, line 14, a different method whereby MPO is detected which is present in a reaction mixture and not that which is immunocaptured. Thus, any MPO enzyme present is not bound to any antibodies at all. This method is unrelated to and otherwise not combinable with the method described in Deby et al. at col. 21, lines 37-64 described above.

On page 3 at the last paragraph of the Office Action, the Examiner asserts that the kit in Deby et al. includes a chromogenic substrate effective for detecting and measuring the enzyme, namely paranitrophenyl phosphate, o-dianisidine, orthophenylene diamine. However, this is incorrect. The first substance is used as a substrate for the alkaline phosphate in the first assay (ELISA described at col. 21, lines 37-64) and the second and third substances are used as substrates for the MPO in the second assay (MPO measurement in solution described at col. 21, line 64 though col. 22, line 14). Therefore, this characterization is incorrect.

Contrary to the Office Action's assertion, at no point does Deby et al. refer to detecting and/or measuring the activity of immunocaptured enzyme present which indicates the activation status of the neutrophil cells. Therefore, for at least this reason, this rejection should be withdrawn and the claims allowed.

Claim Rejections — 35 U.S.C. § 103

Claims 20, 21, and 36 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deby et al. in view of Hansel et al. WO 99/61907 ("Hansel et al.). Claim 22 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deby et al. in view of Deby-Dupont et al., Equine Neutrophil Myeloperoxidase in Plasma: design of a radio-immunopathology 66:257-271 (1998) ("Deby-Dupont et al."). Claims 33, 34, 38, and 39 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deby et al. in view of Terao et al. U.S. Patent No. 5,290,679 ("Terao et al."). Claim 35 is rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Deby et al. in view of Wilson et al. U.S. Patent Application Publication 2006/0257879 ("Wilson et al."). These rejections should be withdrawn as the cited references fail to disclose or suggest one or more features recited in the claims.

Applicants again assert that Deby et al. fails to disclose or suggest one or more features recited in independent claims 15 and 26, from which claims 20, 21, and 34-39 depend. The other cited references similarly fail to disclose or suggest these features such that this rejection should be withdrawn and the claims allowed.

Additionally, the proposed combination fails to disclose or suggest other features recited in the claims. The Office Action alleges that one skilled in the art would combine Deby et al. and Hansel et al. More specifically, the Office Action alleges that the anti-MPO antibodies in Deby et al. would be combined into the method of Hansel et al. to immunologically capture and detect active enzymes released by neutrophils.

As noted in the previous response, Hansel et al. does not distinguish neutrophil peroxidase (myeloperoxidase) from eosinophil peroxidase and from that of other peroxidases

present in lymphocytes. Additionally, Hansel et al. does not provide any enabling details as to how to differentiate between measurement of myeloperoxidase activity and eosinophil peroxidase activity. In fact, Hansel et al. fails to disclose the use on an antibody directed to MPO at all. Instead, Hansel et al. specifically describes separating eosinophil peroxidase from myeloperoxidase by separating the cells releasing the enzymes beforehand.

Even more significant is the fact that the cited references fail to disclose or suggest if the MPO which is immunocaptured would still be enzymatically active, which is what is being measured in the present application. Instead, one skilled in the art would expect that combining Deby et al. with Hansel et al. whereby MPO is bound by an anti-MPO antibody would not show enzymatic activity. Therefore, one skilled in the art would not combine Deby et al. with Hansel et al. to achieve the features recited in the present claims.

The remaining references add nothing to overcome this deficiency. Therefore, as each of the cited references, when taken alone or in combination, fails to disclose or suggest one or more features recited in the claims, the rejection should be withdrawn and the claims allowed.

The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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